

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION,
OPIATE LITIGATION**

MDL NO. 2804

THIS DOCUMENT RELATES TO:

Case No. 17-MD-2804

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268;

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

DECLARATION OF MARC E. DANN

I, Marc E. Dann, being first duly sworn as if upon oath, do hereby declare that:

1. I have personal knowledge of the facts stated in this declaration and, if called to testify, I could and would testify to the matters stated herein.
2. I am the managing partner of DannLaw , and serve as one of the class Counsel for the NAS Guardian Plaintiffs in this matter.
3. I make this Declaration in support of NAS Guardian Plaintiffs' Motion to Compel.

Brief Summary of the Nature of the Case and Procedural Posture

4. On July 11, 2019, this Court ruled that “the undersigned is willing to grant Plaintiffs an abbreviated period to review the available discovery, but absent some showing that the available discovery is insufficient, the Court declines to grant Plaintiff additional discovery at this time.” [Rec. Doc. 1829] (emphasis added).

5. On October 7, 2019, Guardian Plaintiffs amended their class action complaints [September 17, 2019 Non-Document Order] on cases NAS Guardian Plaintiffs filed on behalf of children who suffer from neonatal abstinence syndrome (“NAS”) and to litigate certification of these classes before the end of the year.

NAS Plaintiffs’ Efforts to Access and Review Discovery

6. Although NAS Guardian Plaintiffs spent a year and a half working through the process, waiting for data, discovery and filings, and agreeing to execute acknowledgements of and consent to protective orders as well as PEC imposed participation agreements, NAS Plaintiffs’ access to information was delayed, and the information ultimately provided was limited and insufficient.

7. The history of disclosures to NAS Guardian Plaintiffs is as follows:

8. NAS Guardian Plaintiffs have been seeking discovery for well over a year.

9. Contrary to the earlier understanding of the Court, NAS Guardian Plaintiffs had **not** had access to the Defendants’ discovery provided to the PEC.

10. On July 10, 2019, NAS Guardian Plaintiffs delivered a letter to both Plaintiffs’ Liaison Counsel and the Special Masters advising them that the NAS Guardian Plaintiffs still have not received access to the Defendants’ discovery.

11. The PEC first shared access to ARCOS only as of July 12, 2019, notwithstanding this Court's prior order granting access on June 24, 2019. *See* NAS Guardian Plaintiffs' Motion to Modify Protective Orders re DEA's ARCOS/DADS Database [Rec. Doc. 1704] – Granted on June 24, 2019, Order [Rec. Doc. 1725].

12. Also, on July 12, 2019, the PEC finally shared access to the non-ARCOS discovery documents and transcripts by delivering the Relativity Database.

13. On July 22, 2019, NAS Guardian Plaintiffs requested an expedited case management conference to resolve outstanding discovery issues that deprive Plaintiffs of a full opportunity for discovery and, also, to identify that additional discovery to allow Plaintiffs to identify and certify a class. Because the discovery, including ARCOS data, had not been available until July 12, 2019, it was both unfair and unreasonable to assume that the NAS Guardian Plaintiffs would be able to properly review and evaluate what additional discovery will be necessary until such time as all material and relevant search terms are run, the NAS Guardian Plaintiffs have an opportunity to review in excess of 130-150 million pages of discovery, and other formal discovery documents and sealed documents that were to be made available for the NAS Guardian Plaintiffs' review.

14. On July 26, 2019, in its Order Regarding NAS Guardian Plaintiff Motions [Rec. Doc. 2030] this Court recognized that the NAS Guardian Plaintiffs' Counsel stated that they had “not received sufficient discovery.” This Court ordered:

“This Court also makes clear that all Counsel of record for the NAS Baby [NAS Guardian] cases are entitled to review all formal discovery requests and responses, all existing discovery, and any documents that have been placed under seal, once Counsel has signed any required protective orders and discovery sharing agreements. The PEC shall undertake to provide this access to NAS Baby Counsel as soon as possible”.

July 26, 2019 Order Regarding NAS Motions [Rec. Doc. 2030] (emphasis added).

15. NAS Guardian Counsel have diligently worked with PEC Counsel to receive all the ordered documents which were to be produced in tranches.

16. Over the past three months, a team of attorneys have reviewed millions of documents and Relativity data and had been unable to locate the formal discovery ordered to be produced.

17. After making their best efforts to search through that massive 30 million document database, NAS Guardian Plaintiffs' Counsel found some of the "formal discovery" but were not able to identify the complete set of formal discovery except those fragmented segments located in different locations in the massive database.

18. Declarations were made by the PEC and Plaintiffs' Liaison Counsel that the NAS Baby Guardian's interests were being protected, but as of September 12, 2019, NAS Guardian Plaintiffs had not received any of the discovery requests and responses, and the 30(b)(6) notices addressing the NAS Guardian issues.

19. Not until Monday, September 16, 2019 at 9:29 pm did NAS Plaintiffs receive an email link to a collection of discovery issued by the PEC and formal written responses by a number of the Defendants.

20. Since only July 12, 2019, NAS Guardian Plaintiffs' Counsel have had access to a collection of 160,000,000 pages of documents provided by the Defendants in response to discovery propounded by the PEC in cases brought on behalf of local governments. Initial review of those documents revealed that the PEC's discovery efforts did not yield documents or testimony related to the medical issues implicated in the NAS Guardian Plaintiffs' putative class

actions but, without the underlying discovery requests not received until September 16, 2019, it was impossible to issue new discovery without the risk of retreading ground already plowed by the PEC.

21. Only in the past weeks were NAS Guardian Plaintiffs given access to formal discovery requests and responses as well as 30(b)(6) deposition notices.

Plaintiff-Specific Records and Key Medical Evidence Have Not Been Disclosed

22. While the collection of discovery and responses provided remains incomplete,¹ the discovery requests and responses provided were sufficient to identify areas of inquiry germane to medical monitoring that were either not propounded or that the responses were inadequate for the medical monitoring issues presented by the above-styled cases.

23. It is not surprising that the PEC discovery did not delve into these issues of medicine and science. Cities and counties are claiming economic damages while the claims here stem from complex medical issues.

24. By way of example, below are several statements found in a Purdue package inserts filed with the FDA that reference medical and scientific studies not found in the discovery adduced by the PEC that are specifically relevant to NAS Guardian Plaintiffs’:

- a. “Female subjects have on average plasma oxycodone concentrations up to 25% higher than males on a body weight adjusted basis. The reason is not known”.
PDD8003167492.

¹ For three defendants, folders for the discovery were empty. For at least fourteen defendants, the PEC provided their discovery requests but not the Defendants’ responses. For four defendants, responses and objections to 30(b)(6) notices were missing. Motley Rice was notified of these deficiencies on September 18, 2019 and we are awaiting a response..

- b. “There are no well-controlled studies in women, but marketing experience does not include any evidence of adverse effects on fetuses following routine (short-term) clinical use of morphine sulfate products”. PDD8003167730.
 - c. “The ratio of umbilical venous and maternal concentration of levobupivacine ranged from 0.252-0.303 after epidural administered of levobupivacine cesarean section. These are within the range normally seen for bupivacine”. PDD8003167704.
 - d. Reference is made to assays finding no mutagenic impacts and to assays finding clastogenic impacts. Rat and rabbit studies are cited for the proposition that opioids are not teratogenic. These studies were not cited, named or footnoted. PDD8003167495.
25. Such questions of medicine and science matter to claims being pursued by the NAS Guardian Plaintiffs. For example, if the package insert was inconsistent with the observations noted in the actual study that would present a common question of fact relevant to the risk of latent disease prong of a medical monitoring claim.
26. Given that the Defendants have already produced tens of millions of documents, answering the limited discovery attached should not be overly burdensome.²

² The recent filing of bankruptcy by Defendant Purdue [Rec. Doc. 2609] will require Baby Plaintiffs to seek relief in the Bankruptcy Court to secure discovery from Purdue.

Discovery Requests Currently in Dispute

27. Written Discovery was initially propounded pursuant to the court's scheduling order on October 15, 2019. Attached hereto as "Exhibits A, B, C, and D" are the identical requests propounded by the four groups of Plaintiffs seeking class certification.

28. This written Discovery related to class certification is extremely limited and falls into two categories: (1) Prescription records that relate to the specific Plaintiffs in the four putative class certification cases; and (2) Documents Related to certain clinical studies conducted by Defendants.

29. The relationship between the records of the individual Plaintiffs who are seeking to become class representatives and the upcoming class certification are obvious as they are necessary to establish that the Guardians who seek to represent the class are in the best position to do so.

30. On the medical studies, NAS Guardian Plaintiffs assert claims for medical monitoring which requires proof that the Defendants have tortiously exposed the Plaintiffs to a toxin which creates a risk for serious latent disease. Outstanding discovery requests medical and scientific documents in the possession of the Defendants related to the negative health impacts associated with exposure to opioids in utero which would inform an inquiry into the risk of latent negative health impacts and disease outcomes. One example of the such medical and scientific documents would be those which relate to mare-offspring testing to determine any latent effects revealed in animal testing.

31. While reference is made throughout all of the Defendants' FDA filings to rat and rabbit studies that purportedly determined that opioids are not teratogenic, undersigned Counsel

cannot locate those animal studies or any other mare-offspring scientific studies in the discovery documents to which the PEC gave us access.³ Any such studies relied upon by the manufacturer are common evidence germane to the issue of substantial risk of latent disease associated with exposure to opioids in utero. To be clear, NAS Plaintiffs seek all medical and scientific documents described in the Plaintiffs' outstanding discovery requests and those requests are not limited to mare-offspring studies.

32. In addition to implicating the issues directly related to medical monitoring claims, the medical and scientific documents sought also implicate the NAS Guardian Plaintiffs' claims related to RICO and civil conspiracy because all of the Defendants' seem to be consistently putting forth scientific conclusion that appear to be inconsistent with published, generally accepted science. Plaintiffs' experts have identified numerous articles in medical and scientific journals that seem to directly contradict the representations of the Defendants in the above-mentioned Defendant submissions to the FDA. This apparent inconsistency between the Defendants' representations to the FDA and available medical literature frames a common question of fact that goes directly to the tort allegations that form the basis of the medical monitoring claims asserted.

³ Any such studies relied upon by the manufacturer are common evidence germane to the issue of substantial risk of latent disease associated with exposure to opioids in utero. To be clear, Plaintiff seek all medical and scientific documents described in the Plaintiffs' outstanding discovery requests and those requests are not limited to mare-offspring studies.

Attempts to Resolve Outstanding Discovery Disputes

33. On October 24, 2019, Terry Henry sent a letter on behalf of most of the Defendants that took the following position:

The Defendants identified in your discovery requests do not intend to serve formal responses to Plaintiffs' discovery requests for the following reasons: (i) Judge Polster has not authorized Plaintiffs to conduct discovery; (ii) much of the discovery Plaintiffs seek is unrelated to class certification or is equally available to Plaintiffs; and (iii) Defendants have already produced a prodigious amount of discovery available to Plaintiffs.

(“Exhibit E” hereto October 24, 2019 Letter from Terry Henry, “Defendants’ Response to Plaintiffs’ Discovery Requests”) (see also “Exhibit F” October 24, 2019 Letter from Kevin Sadler on behalf of Asserto Therapeutics Inc.)

34. NAS Guardian Plaintiffs’ Counsel accepted Defendants’ invitation to meet and confer and on Friday October 25, 2019 a conference call was conducted between Counsel to attempt to find a resolution to this standoff on the issue. No resolution was reached.

35. On October 28, 2019, I sent a letter to Counsel seeking clarification on their position and requesting that Counsel for Defendants direct Counsel for NAS Guardian Plaintiffs to the Bates stamps or other identifying numbers of already produced documents that Defendants believe are responsive the NAS Guardian Plaintiffs’ requests. (“Exhibit G” hereto October 29, 2019 Letter from Marc Dann to Defendants’ Counsel).

36. On October 30, 2019, Defendants’ sent correspondence again refusing to identify the documents requested (“Exhibit H” hereto October 30, 2019 Letter from Terry Henry to Plaintiffs’ Counsel).

37. After extensive efforts at resolution Defendants maintain their position that they are not obligated to direct Plaintiffs’ Counsel to the requested documents.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed on this 1st day of November, 2019 in the County of Cuyahoga, State of Ohio.

/s/Marc E. Dann

Marc E. Dann (0039425)